DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

g1781d

September 24, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 – 77

Michael K. Steinhauser
President
Robin Drug Corporation
c/o Merwin Drug Robbinsdale
4098 Lakeland Avenue North
Robbinsdale, MN 55422

Dear Mr. Steinhauser:

During our inspection of your drug repackaging facility, Reed Drug, on August 6 and 17, 2001, located at 4425 South Lake Avenue, White Bear Lake, MN, our investigator found serious violations of the Current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Your drug products are adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The violations observed during our inspection include, but are not limited to, the following:

1. Failure to have a designated quality control unit [21 CFR 211.22].

2. Failure to provide training in current good manufacturing practices for personnel responsible for re-packing and labeling drug products [21 CFR 211.25].

3. Failure to have specifically designated areas for operations such as:

   • Receipt, identification, storage, and withholding of components, drug product containers, closures and labeling pending sampling or exam by the quality control unit [21 CFR 211.82].

- Holding rejected components, drug product containers, closures and labels prior to disposition [21 CFR 211.89].

- Storage of released components, drug product containers, closures and labels [21 CFR 211.122].

- Packaging and labeling operations [21 CFR 211.130].

- Quarantine storage before release of drug products [21 CFR 211.142].

4. Failure to have a written testing program to assess the stability characteristics of the drug products. Also, failure to have stability data to assess whether or not the expiration date is appropriate [21 CFR 211.166].

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction. This is official notification that FDA expects all your locations to be in compliance.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District

CAH/ccl